



Food and Drug Administration  
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July 12, 2016

GC Americica Inc.  
Mark Heiss, D.D.S.  
Director, Regulatory and Academic Affairs  
3737 W 127<sup>th</sup> Street  
Alsip, Illinois 60803

Re: K153325  
Trade/Device Name: GRADIA PLUS  
Regulation Number: 21 CFR 872.3690  
Regulation Name: Tooth shade resin material  
Regulatory Class: II  
Product Code: EBF  
Dated: June 2, 2016  
Received: June 3, 2016

Dear Dr. Heiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

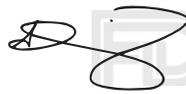
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina  
Kiang -S

for Erin I. Keith, M.S.  
Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Section 4 – Indications for Use Statement

510(k) Number (if known): K153325

Device Name: GRADIA PLUS

Indications for Use:

1. Crown and Bridgework (with metal backing)
2. Metal free restorations: Jacket Crowns, Inlays, Onlays and Laminated Veneers
3. Implant superstructures
4. Reproduction of gum tissue for crown restorations

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

## Section 5 – 510(k) Summary



GC AMERICA INC.  
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1. Submitter Information:

GC AMERICA INC.  
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 Alsip, IL 60803

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Date Prepared: June 1, 2016

2. Device Name:

Proprietary Name: GRADIA PLUS  
 Classification Name: Tooth shade resin material  
 Device Classification: Class II, 872.3690  
 Product Code: EBF

3. Predicate Devices:

| Company         | Device                    | 510(k) No. | Date Cleared | Predicate |
|-----------------|---------------------------|------------|--------------|-----------|
| GC America Inc. | GRADIA                    | K001518    | 07/05/2000   | Primary   |
| GC America Inc. | GRADIA gum shades         | K033808    | 02/02/2004   | Reference |
| GC America Inc. | G-aenial Sculpt (MFP-051) | K123631    | 07/23/2013   | Reference |
| GC America Inc. | OPTIGLAZE color           | K133836    | 03/06/2014   | Reference |

4. Description of Device:

GRADIA PLUS is a dental composite consisting of cross-linked polymeric material reinforced by a dispersion of filler particles bonded to the resin matrix. The product contains a photo initiator to allow for curing/conversion. The end result is a conversion from a paste to a hard solid material.

GRADIA PLUS is composed of 4 types of pastes, such as Opaque paste, Body paste, Gum shade paste and Lustre paint.

Opaque paste is used for masking the metal color.

Body paste has two different consistencies, Paste HB and Paste LB. Both pastes can be used for creating several types of anterior or posterior restorations. There are several shades for dentin shade, Enamel shade and effect shade. The dentin layers have an enhanced brightness and masking ability that adjusts the opalescence of the composites. This gives a bright color tone in the oral cavity and eliminates unnatural translucency at the incisal edge.

In addition, it has several red colors as a Gum shade paste with different transparency and color tone for reproducing of gingival tissue over crown.

Lustre Paint is used for staining, characterizing and coating.

The device is used for crown and bridgework with metal backing, jacket crowns, inlays, onlays, veneers, implant super structures and reproduction of gum tissue for crown restorations. In particular, Gradia Plus is intended to fabricate the tertiary element/exostructure of the implant superstructure, such as crown and bridges.

GRADIA PLUS is filled in a syringe and is available in 73 shades: HB-DA1, HB-DA2, HB-DA3, HB-DA3.5, HB-DB1, HB-DB3, HB-DC3, HB-DD2, HB-DW, HB-ODA, HB-ODB, HB-ODC, HB-ODD, HB-ODW, HB-EL, HB-ED, HB-CLF, HB-PE, LB-BaseD, LB-BaseE, LB-BaseCLF, LB-BaseOD, LB-BaseOpal, LB-DW, LB-ODW, LB-Orange, LB-Red, LB-Yellow, LB-Blue, LB-Grey, LB-Milky, LB-Inlay E, LB-Inlay TD, LB-A, LB-B, LB-C, LB-D, LB-W, GLB-1, GLB-2, GLB-3, GLB-CL, GHB-1, GHB-2, GHB-3, GHB-CL, O-BASE, OA, OB, OC, OD, OA1, OA2, OA3, OA3.5, OB1, OB3, OC3, OD2, GO-1, GO-2, LP-A, LP-B, LP-C, LP-D, LP-CLF, LP-Blue, LP-Cream, LP-Grey, LP-Lavender, GLP-Bright red, GLP-Violet, LP-CL

#### 5. Performance Bench Tests

It is confirmed that the device conforms to the required specifications of ISO 10477:2004 and company standard are suitable for its intended use. Performance testing includes:

- Sensitivity to ambient light
- Depth of cure
- Surface finish
- Flexural strength
- Water sorption
- Solubility
- Shade consistency
- Color stability

#### 6. Packaging

- 1) OPAQUE, 2.0mL syringe (in 13 shades)  
O-BASE, OA, OB, OC, OD, OA1, OA2, OA3, OA3.5, OB1, OB3, OC3, OD2
- 2) PASTE HB, 3.3mL syringe (in 18 shades)  
HB-DA1, HB-DA2, HB-DA3, HB-DA3.5, HB-DB1, HB-DB3, HB-DC3, HB-DD2, HB-DW, HB-ODA, HB-ODB, HB-ODC, HB-ODD, HB-ODW, HB-EL, HB-ED, HB-CLF, HB-PE
- 3) PASTE LB, 2.0mL syringe (in 15 shades)  
LB-BaseD, LB-BaseE, LB-BaseCLF, LB-BaseOD, LB-BaseOpal, LB-DW, LB-ODW, LB-Orange, LB-Red, LB-Yellow, LB-Blue, LB-Grey, LB-Milky, LB-Inlay E, LB-Inlay TD
- 4) ONE BODY, 2.0mL syringe (in 5 shades)  
LB-A, LB-B, LB-C, LB-D, LB-W
- 5) GUM SHADES, 2.0mL syringe (in 10 shades)  
GO-1, GO-2, GLB-1, GLB-2, GLB-3, GLB-CL, GHB-1, GHB-2, GHB-3, GHB-CL
- 6) LUSTRE PAINT, 0.8mL syringe (in 12 shades)  
LP-A, LP-B, LP-C, LP-D, LP-CLF, LP-Blue, LP-Cream, LP-Grey, LP-Lavender, GLP-Bright red, GLP-Violet, LP-CL

Accessories

- 1) MODELING LIQUID 3mL Bottle
- 2) LP DILUTING LIQUID 3mL Bottle
- 3) AIR BARRIER 10mL Bottle
- 4) SEPARATOR 5mL Bottle
- 5) DIE-HARDNER 5mL Bottle

7. Shelf Life Evaluation and Storage Conditions:

- Shelf Life 3 years
- Recommended for optimal performance, store in a cool place (4-25°C / 39.2-77.0 °F) away from high temperatures of direct sunlight.

8. Indications for Use:

1. Crown and Bridgework (with metal backing)
2. Metal free restorations: Jacket Crowns, Inlays, Onlays and Laminated Veneers
3. Implant superstructures
4. Reproduction of gum tissue for crown restorations

9. Technological characteristics:

All the components of the applicant device, GRADIA PLUS, have already been used in the predicate devices. GRADIA PLUS contains ultra-fine barium glass and pre-polymerized filler which exhibit wear resistance and gloss retention. The applicant device also shows equivalence in flexural strength, water sorption and solubility, which indicate the stability of materials in oral environment. The curing mechanism of the predicates and GRADIA PLUS is polymerization of uncured methacrylate ester monomers. This reaction is caused by photo initiator system.

10. Substantial equivalence

The curing mechanism of the new and predicate devices is substantially equivalent in principle. Therefore, the applicant and primary predicate device are the same in function, and similar in composition and intended use. This supports that the compatibility of the applicant device is substantially equivalent to the primary predicate device.

11. Differences

The following differences may be noted between the predicate device and GRADIA PLUS:

- GRADIA PLUS is available in 73 shades
- GRADIA PLUS is available in 5 types of paste: Paste HB, Paste LB, Gum Shade LB, Opaque, Lustre Paint (Stain)
- GRADIA PLUS is used for crown and bridgework with metal backing, jacket crowns, inlays, onlays, veneers, implant super structures and reproduction of gum tissue for crown restorations. The difference is that Gradia is not indicated for shade reproduction of gum tissue. However, this indication is found in Gradia Gum, K033808.
- Applicant device requires coating or polishing as a surface finish. Gradia requires only polishing and Optiglaze Color requires only Coating.
- Gradia uses light-cured hybrid fillers, while Gradia Plus uses light-cured nano fillers.
- Gradia Plus has improved surface gloss which utilizes coating and polishing versus primary predicate only requiring polishing.

**Table 5.1 Substantial equivalence to the primary predicate device (GRADIA)**

|                      | <b>Applicant device</b>   | <b>Primary Predicate device</b>   | <b>Difference<br/>Y/N</b> | <b>Impact on Effectiveness and<br/>rationale</b>  |
|----------------------|---|---|---------------------------|---|
| <b>Trade name</b>    | <b>GRADIA PLUS</b>  | <b>GRADIA</b>   |                           |   |
| Product category     | Light-cured composite for crown and bridge  | Light-cured composite for crown and bridge  |                           |   |
| Company              | GC Corporation  | GC Corporation  |                           |   |
| 510(k) No.           | K153325   | K001518   |                           |   |
| Number of shades     | 73  | 137   | Y                         | Shade number does not impact on safety or efficacy.   |
| Indications for use  | <ol style="list-style-type: none"> <li>1. Crown and Bridgework (with metal backing)</li> <li>2. Metal free restorations: Jacket Crowns, Inlays, Onlays and Laminated Veneers</li> <li>3. Implant superstructures</li> <li>4. Reproduction of gum tissue for crown restorations</li> </ol> | <ol style="list-style-type: none"> <li>1. Crown and Bridgework (with metal backing)</li> <li>2. Metal free restorations: Jacket Crowns, Inlays, Onlays and Laminated Veneers</li> <li>3. Implant superstructures</li> </ol>                           | Y                         | Applicant device includes for reproduction of gum tissue. Comparative device does not include for reproduction of gum tissue. Product performs within requirements. |
| Product description  | GRADIA PLUS is a light-cured nano-filled radiopaque composite resin filled in a syringe. The device is used for crown and bridgework with metal backing, jacket crowns, inlays, onlays, veneers, implant super structures and reproduction of gum tissue for crown restorations.          | GRADIA is a light-cured hybrid MFR (micro-filled-resin) hard resin for laboratory fabrication of crown & bridge, jacket crowns, inlays, onlays and laminated veneer restorations. Gradia can be used for both metal free and metal based restorations | Y                         | Applicant device includes for reproduction of gum tissue. Comparative device does not include for reproduction of gum tissue. Product performs within requirements. |
| Instructions for use | <ol style="list-style-type: none"> <li>1.Preparation</li> <li>2.Treatment</li> <li>3.Build up</li> <li>4.Light curing</li> <li>5.Glazing (Coating and Polishing)</li> </ol>   | <ol style="list-style-type: none"> <li>1.Preparation</li> <li>2.Treatment</li> <li>3.Build up</li> <li>4.Light curing</li> <li>5. Polishing</li> </ol>  | Y                         | Applicant device requires coating or polishing as a surface finish. Predicate device requires only polishing. Product performs within requirements.                 |

**Table 5.2 Substantial equivalence to the reference predicate device (GRADIA GUM)**

|                      | <b>Applicant device</b>   | <b>Reference Predicate device</b>   | <b>Difference Y/N</b> | <b>Impact on Effectiveness and rationale</b>   |
|----------------------|---|---|-----------------------|--|
| <b>Trade name</b>    | <b>GRADIA PLUS</b>  | <b>GRADIA gum shades</b>  |                       |  |
| Product category     | Light-cured composite for crown and bridge  | Light-cured gum shades composite system   |                       |  |
| Company              | GC Corporation  | GC Corporation  |                       |  |
| 510(k) No.           | K153325   | K033808   |                       |  |
| Shade number         | 73  | 17  | Y                     | Shade number does not impact on safety or efficacy.  |
| Indications for use  | <ol style="list-style-type: none"> <li>1. Crown and Bridgework (with metal backing)</li> <li>2. Metal free restorations: Jacket Crowns, Inlays, Onlays and Laminated Veneers</li> <li>3. Implant superstructures</li> <li>4. Reproduction of gum tissue for crown restorations</li> </ol> | GRADIA GUM is a light-cured composite resin specifically used for the reproduction of the gum on crown and bridge prostheses.   | Y                     | Applicant device is for crown , inlays, onlays, veneers, Implant superstructure and shade reproduction of gum tissue. Comparative device is only for gum tissue, such as implant superstructures and removable metal frames. Product performs within requirements. |
| Product description  | GRADIA PLUS is a light-cured nano-filled radiopaque composite resin filled in a syringe. The device is used for crown and bridgework with metal backing, jacket crowns, inlays, onlays, veneers, implant super structures and reproduction of gum tissue for crown restorations.          | GRADIA gum shades is a light-cured MFR (micro-filled-resin) composite for reproduction of gum tissue for crown restorations including implant superstructures and removal of metal frames. Five gum shades are available along with the Opaque, Translucent, Modifiers and Accessories. | Y                     | Applicant device is for crown, inlays, onlays, veneers, Implant superstructure and reproduction of gum tissue. Comparative device is only for gum tissue, such as implant superstructures and removable metal frames. Product performs within requirements.        |
| Instructions for use | <ol style="list-style-type: none"> <li>1.Preparation</li> <li>2.Treatment</li> <li>3.Build up</li> <li>4.Light curing</li> <li>5.Glazing (Coating and Polishing)</li> </ol>   | <ol style="list-style-type: none"> <li>1.Preparation</li> <li>2.Treatment</li> <li>3.Build up</li> <li>4.Light curing</li> <li>5. Polishing</li> </ol>  | Y                     | Applicant device require coating or polishing as a surface finish. Predicate device require only polishing. Product performs within requirements.  |

**Table 5.3 Substantial equivalence to the reference predicate devices (G-aenial Sculpt and Optiglaze Color)**

|                             | <b>Applicant device</b>   | <b>Reference devices</b>  |  | <b>Difference Y/N</b> | <b>Impact on Effectiveness and rationale</b>   |
|-----------------------------|---|---|--|-----------------------|--|
| <b>Trade name</b>           | <b>GRADIA PLUS</b>  | <b>G-aenial Sculpt (MFP-051)</b>  | <b>OPTIGLAZE color (Nanocoat color)</b>  |                       |  |
| <b>Product category</b>     | Light-cured composite for crown and bridge  | Light-cured composite restorative   | Light-cured characterization material  |                       |  |
| <b>Manufacturer</b>         | GC Corporation  | GC Corporation  | GC Corporation   |                       |  |
| <b>510(K) No.</b>           | K153325   | K123631   | K133836  |                       |  |
| <b>Number of Shades</b>     | 73  | 17  | 17   | Y                     | Shade number does not impact on safety or efficacy.  |
| <b>Indications for use</b>  | <ol style="list-style-type: none"> <li>1. Crown and Bridgework (with metal backing)</li> <li>2. Metal free restorations: Jacket Crowns, Inlays, Onlays and Laminated Veneers</li> <li>3. Implant superstructures</li> <li>4. Reproduction of gum tissue for crown restorations</li> </ol> | <ol style="list-style-type: none"> <li>1. Direct restorative for class I, II, III, IV, V cavities.</li> <li>2. Direct restorative for wedge-shaped defects and root surface cavities.</li> <li>3. Direct restorative for veneers and diastema closure.</li> </ol> | <ol style="list-style-type: none"> <li>1. Characterization of direct &amp; indirect composite restorations, acrylic denture base and artificial acrylic teeth.</li> <li>2. For obtaining surface smoothness and wear resistance of restorations made of composite resin, acrylic denture base and artificial acrylic teeth.</li> </ol> | Y                     | <p>Applicant device includes for reproduction of gum tissue. Comparative devices do not include for reproduction of gum tissue.</p> <p>Product performs within requirements.</p> |
| <b>Product description</b>  | GRADIA PLUS is a light-cured nano-filled radiopaque composite resin filled in a syringe. The device is used for crown and bridgework with metal backing, jacket crowns, inlays, onlays, veneers, implant super structures and reproduction of gum tissue for crown restorations.          | G-aenial Sculpt (MFP-051) is a light cured nano-filled radiopaque composite resin filled in a syringe and unitip. The device is used for the restorations of both anterior and posterior teeth  | OPTIGLAZE Color is a light-cured glazing and characterizing material for such restorations as direct and indirect composites. It is also used for obtaining surface smoothness and wear resistance of restorations made of composite resins and acrylics. The material is available in 17 shades.                                      | Y                     | <p>Applicant device requires coating or polishing as a surface finish.</p> <p>Product performs within requirements.</p>  |
| <b>Instructions for Use</b> | <ol style="list-style-type: none"> <li>1. Preparation</li> <li>2. Treatment</li> <li>3. Build up</li> <li>4. Light curing</li> <li>5. Glazing (Coating and Polishing)</li> </ol>  | <ol style="list-style-type: none"> <li>1. Cavity Preparation</li> <li>2. Bonding Treatment</li> <li>3. Placement</li> <li>4. Light Curing</li> <li>5. Finishing and polishing</li> </ol>  | <ol style="list-style-type: none"> <li>1. Preparation</li> <li>2. Clean and dry</li> <li>3. Apply</li> <li>4. Light curing (Coating)</li> </ol>  |                       |  |

12. Conclusion

Based on formulation, testing and meeting and/or exceeding ISO standards related to performance, we find the applicant device substantial equivalent to the noted predicates.